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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,632	12/26/2001	Timothy J. Brennan	P05435US0	9250

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 10/033,632	Applicant(s) BRENNAN, TIMOTHY J.	
	Examin r Konata M. George	Art Unit 1616	

-- The MAILING DATE f this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-5 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on May 19, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. Examiner acknowledges the cancellation of claims 6-10.

Response to Arguments

3. Applicant's arguments filed May 15, 2003 have been fully considered but they are not persuasive.

Applicants' argue that Arnold teaches the use of 6-[2-(1(2)H-tetrazole-5-yl)ethyl]decahydroisoquinoline-3-carboxylic acid as an analgesic agent, however, the claimed invention is used for anesthesia. Applicants also argue that Arnold does not teach the method of delivery of the agent. Applicants claim that their invention is used as a spinal anesthesia; however, the claim read that the compound is giving in a small anesthetic producing amount. It is the position of the examiner that a small anesthetic producing amount of the drug would not have the same effects as an anesthesia. Anesthesia can be defined as a loss of normal feeling or sensation, an anesthetic is a

drug that causes unconsciousness or a loss of general pain and an analgesic is an agent that alleviates pain. Therefore, since the claim states that the composition is administered "spinally a small anesthetic producing amount" and an anesthetic is a drug that causes loss in general pain and that Arnold teaches the compound used as an analgesic; and an analgesic is an agent that alleviates pain then the prior art reference teaches the claimed invention and is thus obvious. With respect to the method of delivery "Current Therapy" (1977) page 830 describes methods of spinal anesthesia delivery. The last line in the first column through the 3rd line of the second column teaches that a needle is inserted at L3-4, on the vertical line through the interspace but 1 cm below the ridge of the osseomuscular spinal column.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold (US 5,670,516) in view of Current Therapy (1977).

Arnold discloses in claims 36 and 37, column 88, lines 38-44 a formulation comprising a pharmaceutically acceptable carrier together with 6-[2-(1(2)H-tetrazole-5-yl)ethyl] decahydroisoquinoline-3-carboxylic acid or a pharmaceutically acceptable salt

thereof. Column 36, lines 11-12, discloses that the compounds can be used as analgesic agents and column 35, lines 33-38, teaches that the compound can be administered from about 0.01 mg/kg to about 20 mg/kg preferably about 0.1 to about 0.5 mg/kg. Column 35, line 46, teaches the many different types of physiological functions that compound can treat, one of which is spinal cord trauma. The prior art of Arnold does not teach the route of administration being intrathecal.

On page 830 of Current Therapy describes methods of spinal anesthesia delivery. The last line in the first column through the 3rd line of the second column teaches that a needle is inserted at L3-4, on the vertical line through the interspace but 1 cm below the ridge of the osseomuscular spinal column.

It would have been obvious to one of ordinary skill to use the teachings of Current Therapy to select intrathecal administration as the best mode for the purposes of delivery an anesthesia to the spinal cord. As describe on page 830 it is known in the art that when administering an anesthesia to the spinal cord that it would be done by way of intrathecal administration and example of such a practice is administering a drug during pregnancy.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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